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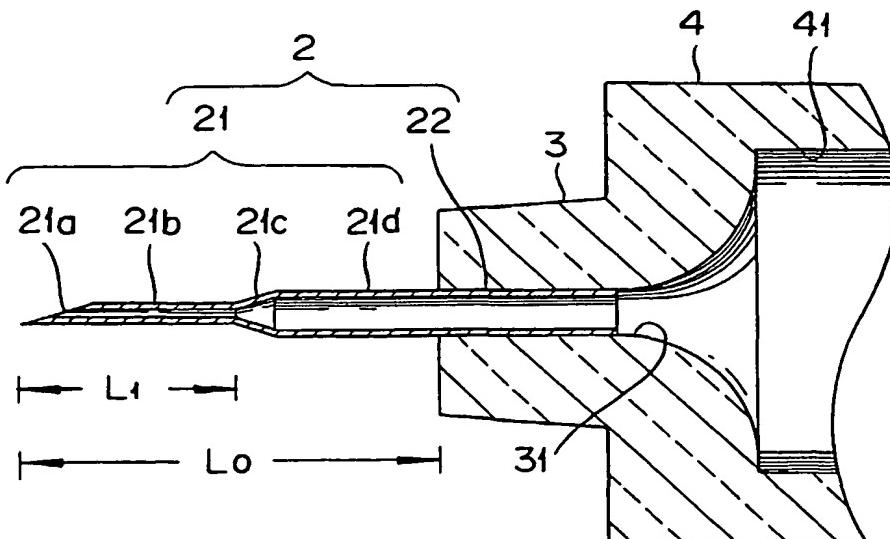
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(54) Title: LIQUID INJECTION NEEDLE AND LIQUID INJECTION DEVICE

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(57) Abstract: A liquid injection needle (10) includes a hollow needle part (2) for injecting a liquid (8) and a supporting part (3), to which the needle part (2) is fixed. The needle part (2) includes an anchoring part (22) that extends through the inside of the supporting part (3) and a puncturing part (21) that extends from the supporting part (3) for making a puncture in a living body. The puncturing part (21) has a distal side outer diameter equal to or greater than 0.1 mm and equal to or less than 0.25 mm, and a proximal side outer diameter greater than the distal side outer diameter.



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## DESCRIPTION

## LIQUID INJECTION NEEDLE AND LIQUID INJECTION DEVICE

## 5 Technical Field:

The present invention generally pertains to a liquid injection needle and a liquid injection device. More particularly, the invention relates to a liquid injection needle and a liquid injection device used for percutaneously injecting drug solutions for living bodies into living bodies intracutaneously, subcutaneously, or intramuscularly.

## Background Art:

An example of a known drug injection device used for injecting drug solutions into living bodies is shown in Fig. 1. The drug injection device 101 includes a needle 102 for injecting a drug solution, a supporting part 103 for supporting the needle 102, a substantially cylindrical shaped main body 104 for containing the drug, and a plunger 105 for injecting the drug contained inside the main body 104. The needle 102 consists of a hollow needle having a constant outer diameter, one end of which is firmly fixed to the supporting part 103, and is capable of communicating with the inner space of the main body 104.

25 However, the needle 102 has an outer diameter larger than 0.3 mm and is relatively thick. As a result, pain may result to the patient when the needle 102 punctures the living body or injects a drug solution into the living body. Also, considering the size of the needle, the thought of being punctured with the needle can cause anxiety to the patient.

Using a thinner needle to reduce the pain and/or anxiety to the patient has its own problems. For example, it is

extremely difficult to fix a thin needle to the supporting part in order to assemble a drug injection device. There is also a concern that a thin needle may be unable to puncture the skin of a living body and may end up bending due to its  
5 lack of physical strength.

Moreover, a thin needle naturally has a small inner diameter, and so an excessively large force may be required to suck the drug solution from a container such as a vial or inject the drug into the living body. Thus, a potential  
10 problem exists in that a thin needle may require a large force for sucking the drug solution from a container or injecting the drug into the living body.

Drug injection devices to be used for percutaneous self-administration of insulin solutions (the solutions containing insulin) by diabetic patients are available on the market. The thinnest outer diameter available on such drug injection devices is 0.254 mm (31G (Gage)). The "Gage" is a number based on the B.W.G. (Birmingham Wire Gage) standard.

Unfortunately, the injection resistance felt in  
20 injecting drug solutions using a 31G needle is substantially large. This is due to the fact that the injection resistance increases theoretically in inverse proportion to the fourth power of the needle diameter.

Therefore, there is a concern that a patient with weak  
25 strength such as a female, child, or aged person may have problem in injecting a drug solution in case of subcutaneous self-administration using a 31G needle because the force usable for pressing the plunger of a drug injection device is poor. In such a case, the patient has no choice but to  
30 use a thicker needle, for example, a needle with an outer diameter of 0.30 mm (30G), which causes less injection resistance, but greater pain.

Another problem in using a 31G needle is that the insulin solution may leak through the punctured hole in the skin or from the tip of the needle. One of the causes of such a problem is the following.

5 A needle as thin as a 31G needle requires a long time to complete the injection of the drug solution as it has a high injection resistance. Consequently, the patient may become impatient and pull the needle out of the skin before the entire administration amount of the drug to be delivered  
10 per injection (i.e., insulin unit) is administered subcutaneously.

The insulin unit is predetermined for each diabetic patient and it is essential to administer an exact amount per each injection. Leakage of the drug solution after  
15 injection means that an amount less than the required amount is administered, hence being unable to provide sufficient curing effect.

In the field of dental treatments, drug injection devices are used for injecting anesthetic drugs, such as lidocaine,  
20 into the patient's dental pulp. The thinnest needle available on the market for drug injection devices for dental use has an outer diameter of 0.26 mm.

A substantially high injection resistance develops when a dental needle with an outer diameter of 0.26 mm is used  
25 for injecting anesthetic drugs into dental pulps and the like. Therefore, the main body of the device and the plunger are made of metals requiring a doctor with a normal, healthy body for injecting an anesthetic drug. Thus, it is possible to inject an anesthetic drug even with such a thin needle, if  
30 a very large force is applied to the plunger.

However, because the device and the plunger are made of metal, the device is relatively heavy and difficult to

handle. If injection resistance can be reduced, lighter materials such as plastics can be used to form the device and injection can be done with less force. Hence, it is possible to provide a lighter and easier to use drug injection 5 device for dental use.

Moreover, as mentioned above, a thicker needle is not preferable as it tends to create anxiety in the patient, although it can reduce injection resistance. In other words, it is preferable to use a thinner needle to reduce or alleviate 10 pain or anxiety to the patient in a dental drug injection device as well.

Thus, although very thin needles can reduce or alleviate pain to the patient, problems exist such as difficulty of manufacture, lack of strength and high injection resistance. 15 Such needles are thus not practically used.

An object of the present invention is to provide a very thin liquid injection needle, and a liquid injection device equipped with such liquid injection needle, that are capable of alleviating pain to the patient, being relatively easy 20 to manufacture, providing sufficient strength, and causing less injection resistance.

#### Disclosure of Invention:

A liquid injection needle of the invention includes a hollow needle part for injecting a liquid and a supporting part to which the needle part is fixed, wherein the needle part comprises an anchoring part that extends through the inside of the supporting part and a puncturing part that extends from the supporting part for making a puncture in a living body. The puncturing part has a distal side outer diameter equal to or greater than 0.1 mm and equal to or less than 30 0.25 mm, and a proximal side outer diameter greater than the

distal side outer diameter.

According to another aspect, a liquid injection needle includes a hollow needle part for injecting a liquid and a supporting part to which the needle part is fixed, wherein  
5 the needle part has an anchoring part that extends through the inside of the supporting part and a puncturing part that extends from the supporting part for making a puncture in a living body. The puncturing part has a proximal side outer diameter greater than a distal side outer diameter and  
10 possesses a sticking resistance equal to or less than 7 gram-force.

In accordance with another aspect, a liquid injection needle includes a hollow needle part for injecting a liquid and a supporting part to which the needle part is fixed, wherein  
15 the needle part has an anchoring part that extends through the inside of the supporting part and a puncturing part that extends from the supporting part for making a puncture in a living body. The puncturing part has a proximal side outer diameter greater than a distal side outer diameter, and the  
20 needle part has a flow path resistance equal to or less than 350 gram-force under a sustained water flow rate of 20  $\mu$  l/sec.

Another aspect involves a liquid injection device provided with the above-described liquid injection needle,  
25 wherein the liquid injection device includes a main body having an internal space adapted to contain the liquid, with the supporting part being provided on one end part of the main body. The needle part of the liquid injection needle is fixed on the supporting part to communicate with the internal space.  
30

#### Brief Description of Drawings:

The foregoing and additional features and

characteristics of the present invention will become more apparent from the following detailed description considered with reference to the accompanying drawing figures in which like reference numerals designate like elements.

5 Fig. 1 is a side view of a known drug injection device.

Fig. 2 is a side view of a drug injection device of an embodiment according to the present invention.

Fig. 3 is a cross-sectional view of the drug injection device shown in Fig. 2.

10 Fig. 4 is a side view of a drug injection needle of the drug injection device shown in Fig. 2.

Fig. 5 is a cross-sectional view of the drug injection needle shown in Fig. 4.

15 Fig. 6 is an expanded cross-sectional view of a drug injection needle according to example 1 used for sticking resistance measurement.

Fig. 7A is a side view of a drug injection needle illustrating a first grinding angle of the drug injection needle.

20 Fig. 7B is a view of a drug injection needle illustrating a second grinding angle of the drug injection needle.

Fig. 7C is a cross-sectional view taken along the section line A-A in Fig. 7A illustrating a cross-sectional angle of the drug injection needle.

25 Fig. 8 is a graph showing sticking resistance measurement results of example 1.

Fig. 9 is a schematic illustration of a flow path resistance measurement system.

30 Fig. 10 is a cross-sectional view of explaining a method for connecting a needle mounting part and a needle part according to the flow path resistance measurement system.

Fig. 11 is a graph showing the results of the flow path

resistance measurement of example 1.

Fig. 12 is a table showing the results of the sticking and flow path resistance measurement of examples 2-12.

Fig. 13 is a cross-sectional view of a drug injection device according to another embodiment.

Fig. 14 is a cross-sectional view of a drug injection device according to another embodiment.

**Best Mode for Carrying Out the Invention:**

Referring initially to Figs. 2 and 3, a drug injection device 1 according to one embodiment includes a drug injection needle 10 and a main body 4. The drug injection needle 10 has a hollow needle part 2 possessing a special shape and a supporting part 3 to which one end of the needle part 2 is firmly fixed. The main body 4 is substantially cylindrical in shape and has an internal space 41 into which a plunger 5 is inserted allowing the plunger 5 to reciprocate longitudinally.

In general, drug solution 8 is sucked from a container such as a vial into the internal space 41 through the needle part 2, and is injected into the living body from the tip of the needle part 2 by pushing the plunger 5 into the main body 4.

The supporting part 3 located on one end (i.e., the left end in Figs. 2 and 3) of the main body 4 has a passage 31 formed to communicate with the internal space 41 of the main body 4. The base of the needle part 2 is fixed in a liquid-tight manner to the internal surface of the passage 31. Therefore, the needle part 2 communicates with the internal space 41 of the main body 4 via the passage 31.

In the illustrated embodiment, the supporting part 3 and the main body 4 are formed integrally. However, it is

also possible to form the supporting part 3 and the main body 4 separately, and fix the supporting part 3 to the end of the main body 4 by way of gluing or welding. It is also possible to detachably mount the supporting part 3 to the end of the main body 4 by way of threading or fitting.

On the other end (i.e., the right end in Figs. 2 and 3) of the main body 4, an opening 42 is provided to insert the plunger 5 into the internal space 41. A gasket 6 is provided on the tip of the plunger 5 that fits closely into the inner wall of the main body 4. The gasket 6 serves a sealing function so that the drug solution does not leak backward when the plunger 5 moves toward the supporting part 3.

The drug solution 8 is, for example, a liquid solution, a gel or a suspension containing a drug. The device is applicable to any drug, as long as it is not a drug unsuitable for percutaneous administration.

Major drugs that can be included in this category are antibacterial drugs, antiviral drugs, vaccines, antineoplastic drugs, immunosuppressive drugs, steroid, antiinflammatory drugs, antirheumatic drugs, arthritis drugs, antihistamic drugs, antiallergic drugs, antidiabetic drugs, hormone agents such as growth hormone, bone calcium metabolic drugs, vitamins, blood products, hematopoietic drugs, antithrombotic drugs, hypolipidemic drugs, antiarrhythmic drugs, vasodilator drugs, prostaglandin, calcium antagonistic drugs, ACE inhibitors,  $\beta$  blockers, antihypertensive drugs, diuretic drugs, xanthine derivatives,  $\beta$  agonists, antasthmatic drugs, antitussive drugs, expectorants, anticholinergic drugs, antidiarrheal drugs, digestants, antiulcer drugs, cathartic drugs, hypnotic drugs, sedative drugs, antipyretic drugs, cold remedies, antiepileptic drugs, antipsychotic drugs, antidepressive

drugs, antianxiety drugs, central nerve irritant drugs, parasympathetic drugs, sympathetic drugs, antiemetic drugs, central stimulants, antiparkinsonism drugs, muscle relaxants, anticonvulsants, anesthetic agents, antipruritic drugs,  
5 migraine drugs, oligonucleotides, gene drugs, etc.

Drugs that are ineffective or become less effective when orally administered, for example, peptide, protein, polysaccharide, oligonucleotide, DNA, etc., are more preferable for this application.

10 The injection amount of the drug solution 8 per each administration is set up equal to the single administration amount of conventional injection drugs, which is 1 ml or less in most cases, or between 0.01 and 2 ml.

15 The gasket 6 is made of butyl rubber, silicone rubber, elastomer, etc., and is formed by a molding process. The supporting part 3, the main body 4, and the plunger 5 are made of plastic materials such as polypropylene, and polyethylene, and formed by a molding process.

20 The main body 4, the supporting part 3, and the plunger 5 are made partially or totally of a transparent material so that the user can visually check the quantity of the drug solution 8 contained in the internal space 41. The surface of the main body 4 has a scale 7 so that the user can check the amount of drug solution 8 contained or injected.

25 The needle part 2 has a puncturing part 21 and an anchoring part 22 as shown in Fig. 4 and Fig. 5. The puncturing part 21 is an extension part protruding outward from the supporting part 3 and is adapted to be stuck into the living body. The anchoring part 22 is an extension part that extends into the  
30 inside of the supporting part 3, and connects or communicates with the passage 31 that communicates with the internal space 41 of the main body 4.

The tip of the puncturing part 21 has a slanted part 21a forming a blade surface that can be stuck into the skin. The blade surface is formed by slicing the tip at an angle.

The distal side outer diameter of the puncturing part 5 21, i.e., the outer diameter of the puncturing part 21 in the vicinity of the slanted part 21a should be equal to or larger than 0.1 mm and equal to or smaller than 0.25 mm, preferably equal to or larger than 0.1 mm and equal to or smaller than 0.23 mm, more preferably equal to or larger than 10 0.1 mm and equal to or smaller than 0.20 mm.

The upper limit of the distal side outer diameter of the puncturing part 21 is set smaller than the conventional size from the standpoint of reducing the sticking pain to the patient. The lower limit is set from the standpoint of 15 securing the desired strength and suppressing the increase of flow path resistance during the drug solution injection. The distal side internal diameter of the puncturing part 21 is preferably equal to or larger than 0.05 mm and equal to or smaller than 0.15 mm, preferably equal to or larger than 20 0.05 mm and equal to or smaller than 0.13 mm, more preferably equal to or larger than 0.05 mm and equal to or smaller than 0.10 mm.

In the process of percutaneous puncture by way of a needle, nociperception is induced generally as a result of the tip 25 of the needle advancing into the deeper area of the skin, tearing up the skin and causing irritation and damage in the nerves and veins related to the pain.

However, the distal side outer diameter of the puncturing part 21 is chosen extremely small in this embodiment. 30 Therefore, irritation and damage in the nerves and veins caused by the slanted part 21a that punctures the skin and tears the living body are minimized. Thus, the puncturing part 21

causes almost no puncturing pain to the patient.

On the other hand, the proximal side outer diameter of the puncturing part 21 is chosen larger than the distal side outer diameter of the puncturing part 21. Therefore, strength 5 sufficient for puncturing the living body with the puncturing part 21 can be secured. This helps prevent the user from causing an accidental breakage of the puncturing part 21 and leaving the puncturing part 21 inside the living body.

Specifically, the proximal side outer diameter of the 10 puncturing part 21 is equal to or larger than 0.3 mm and equal to or smaller than 2 mm, more preferably equal to or larger than 0.35 mm and equal to or smaller than 1.5 mm, most preferably equal to or larger than 0.35 mm and equal to or smaller than 1 mm.

15 The lower limit of the proximal side outer diameter of the puncturing part 21 is chosen larger than the distal side outer diameter of the puncturing part 21 from the standpoint of aggressively reducing the flow path resistance during the drug solution injection as mentioned above. Also, the upper 20 limit of the proximal side outer diameter of the puncturing part 21 is chosen to suppress the sticking resistance into the living body. The proximal side internal diameter of the puncturing part 21 should preferably be equal to or larger than 0.20 mm and equal to or smaller than 1.2 mm, preferably 25 equal to or larger than 0.25 mm and equal to or smaller than 1.0 mm, more preferably equal to or larger than 0.25 mm and equal to or smaller than 0.8 mm.

The total length  $L_0$  of the puncturing part 21 is preferably equal to or larger than 1.5 mm and equal to or smaller than 30 15 mm, more preferably equal to or larger than 3 mm and equal to or smaller than 10 mm. The total length  $L_0$  is defined as the length from the supporting part 3 to the tip of the slanted

part 21a that punctures the skin.

The total length  $L_0$  is normally 8 to 40 mm for conventional subcutaneous or intramuscular administrations. However, the upper limit of the total length  $L_0$  of the puncturing part here 5 is chosen shorter than that from the standpoint of securing a desired strength and suppressing an increase of flow path resistance during injection of a drug solution. The lower limit is chosen from the standpoint of effecting a more smooth puncturing into the living body.

10 The outer diameter of the puncturing part 21 is preferably equal to or larger than 0.1 mm and equal to or smaller than 0.25 mm for a given length  $L_1$  starting from the slanted part 21a toward the supporting part 3. The length  $L_1$  should be set to 2/3 or more, or more preferably 4/5 or more, of the 15 total length  $L_0$  if the total length  $L_0$  is equal to or longer than 1.5 mm and equal to or shorter than 5 mm. If the total length  $L_0$  is longer than 5 mm and equal to or shorter than 15 mm, the length  $L_1$  should be set to 3/5 or more, or more 20 preferably equal to or larger than 3/5 and equal to or shorter than 4/5, of the total length  $L_0$ .

The lower limit of the length  $L_1$  is chosen to minimize the sticking resistance by maintaining the outer diameter of the puncturing part 21 small immediately after skin puncturing by the slanted part 21a. The upper limit of the 25 length  $L_1$  is chosen from the standpoint of securing sufficient strength and suppressing the increase of the flow path resistance as the time of drug solution injection.

The puncturing part 21 in this embodiment has a distal end 21b that contains the slanted part 21a, a proximal end 30 21d that has an outer diameter larger than that of the distal end 21b, and a middle part 21c located between the distal end 21b and the proximal end 21d.

The outer diameter of the middle part 21c changes continuously, and smoothly connects the distal end 21b and the proximal end 21d. The inner diameter of the middle part 21c reduces gradually toward the distal end 21b. Therefore,  
5 the drug solution 8 is accelerated as it passes through the middle part 21c to flow powerfully into the distal end 21b.

The distal end 21b and the proximal end 21d can both be formed to have substantially constant outer diameters for the entire length as shown in the drawing figures or can be  
10 formed to have tapering shapes.

The outer diameter of the anchoring part 22 that extends through the inside of the supporting part 3 is similar to the outer diameter of the proximal end 21d, and should be equal to or larger than 0.3 mm and equal to or smaller than  
15 2 mm, preferably equal to or larger than 0.35 mm and equal to or smaller than 1.5 mm, more preferably equal to or larger than 0.35 mm and equal to or smaller than 1 mm.

The lower limit of the outer diameter of the anchoring part 22 is chosen to be larger than the distal side diameter  
20 of the puncturing part 21 from the standpoint of aggressively reducing the flow path resistance during drug solution injection and increasing the area of junction with the supporting part 3 to enhance the junction strength. The upper limit of the outer diameter of the anchoring part 22 is chosen  
25 from the standpoint of suppressing the increase of the external dimension of the supporting part 3. As a result, the inner diameter of the anchoring part 22 should preferably be set equal to or larger than 0.20 mm and equal to or smaller than 1.2 mm, preferably equal to or larger than 0.25 mm and equal  
30 to or smaller than 1.0 mm, more preferably equal to or larger than 0.25 mm and equal to or smaller than 0.8 mm.

The anchoring part 22 can be formed alternatively to

have its inner diameter increasing gradually toward the passage 31 of the supporting part 3. Doing so will further reduce the flow path resistance so that the drug solution 8 is accelerated as it passes through the anchoring part 22  
5 to flow powerfully into the proximal end 21d.

A suitable range of wall thickness of the needle part 2 varies with the construction such as outer diameters and materials of the puncturing part 21 and the anchoring part 22. Specifically, a distal side wall thickness of the puncturing part 21 is equal to or larger than 20  $\mu\text{m}$  and equal to or smaller than 50  $\mu\text{m}$ , and a proximal side wall thickness of the puncturing part 21 and a wall thickness of the anchoring part 22 are equal to or larger than 50  $\mu\text{m}$  and equal to or smaller than 400  $\mu\text{m}$ , preferably equal to or larger than 50  
10  $\mu\text{m}$  and equal to or smaller than 250  $\mu\text{m}$ , more preferably equal to or larger than 50  $\mu\text{m}$  and equal to or smaller than 130  $\mu\text{m}$ .  
15

The needle part 2 is made of stainless steel, for example, and is formed by a plastic working process. However, the  
20 needle part 2 can alternatively be made of other metals such as titanium, or other materials such as plastics.

The fixing of the needle part 2 to the supporting part 3 is accomplished by an insert forming process or gluing. Since the needle generally has a small outer diameter, its  
25 junction to the supporting part is relatively weak and may fall off from the supporting part. To counter this tendency, the outer diameter of the anchoring part 22 that is fixed to the supporting part 3 is chosen to be larger than the distal side outer diameter of the puncturing part 21 in this  
30 embodiment.

In other words, the needle part 2 is firmly fixed to the supporting part 3 via the anchoring part 22 having a large

diameter to prevent the needle part 2 from falling off. Moreover, since the joint area between the anchoring part 22 and the supporting part 3 is larger, it is easier to securely fix the needle part 2 to the supporting part 3. Therefore, 5 it is easy to manufacture the drug injection needle 10 and the drug injection device 1 despite the fact that the distal side outer diameter of the puncturing part 21 is small.

Next, this embodiment will be described below from the standpoint of the sticking resistance. The sticking 10 resistance is defined by the load experienced in sticking a silicone rubber piece at a speed of 10 mm/sec. The silicone rubber piece is 0.5 mm thick and its hardness, which is detected by a rubber hardness tester (durometer) based on K6253 type A of the Japanese Industrial Standard, is A50 (referring to 15 Section 7619 of the International Organization for Standardization).

Fig. 6 is an expanded cross-sectional view of the needle part 2 according to example 1 used in the measurement of the sticking resistance. As shown in the drawing, the total length 20  $L_0$  of the puncturing part 21 is 8 mm or 13 mm, and the length  $L_1$  of the distal end 21b is 2.75 mm.

The outer diameter and the inner diameter of the proximal end 21d are 0.35 mm and 0.25 mm respectively, and the outer diameter and the inner diameter of the distal end 21b are 25 0.2 mm and 0.1 mm. The length of the middle part 21c in which the outer diameter and the inner diameter gradually reduce is 3.5 mm and the angle between contour line and the axial line shown by the alternating long and short dash line is 1 degree 50 minutes 28 seconds.

30 A first grinding angle  $\alpha$ , a second grinding angle  $\phi$ , and a cross sectional angle  $\gamma$  of the needle part 2 are 8.5, 18 and 129 degrees respectively. As shown in Fig. 7A, the

first grinding angle  $\alpha$  is the basic angle formed between the centerline of the distal end 21b shown by the alternating long and short dash lines and the slanted part 21a. In addition, as shown in Fig. 7B, the second grinding angle  $\phi$  is the angle 5 formed between the cut surface forming the blade surface of the slanted part 21a and the centerline. Further, the cross sectional angle  $\gamma$  is, as shown in Fig. 7C, the angle formed between the edges of the two sides of the blade tip section (referring to Section 7864 of the International Organization 10 for Standardization).

As a reference point, a needle available on the market intended for use on drug injection devices for percutaneous self-administration of insulin solution by diabetes patients was used, with such needle having a constant outer diameter 15 of 0.254 mm and a constant inner diameter of 0.125 mm for the entire length, i.e., a 31G needle was used. The first grinding angle  $\alpha$ , the second grinding angle  $\phi$ , and the cross sectional angle  $\gamma$  of the 31G needle were 9, 22 and 130 degrees respectively.

20 Fig. 8 is a graph showing the measurement result of the sticking resistance of example 1, with the vertical axis and the horizontal axis showing the load and the displacement respectively. As can be seen from Fig. 8, the sticking resistance of the needle part 2 according to the present embodiment is markedly smaller than that of the conventional 31G needle in an area where a peak indicates a maximum load.

It can be seen from the graph that the maximum value 25 of the sticking resistance of the conventional needle 31G is 8.4 gf (gram-force) (82.3 mN) and thus exceeds 8 gf (78.4 mN), while the maximum value of the sticking resistance of the needle part 2 is 6.4 gf (62.7 mN) and is thus less than 30 7gf (68.6 mN). This evidences that the needle part 2 according

to the present embodiment has superior characteristics with respect to the sticking resistance as compared to the 31G needle and is thus capable of reducing the sticking pain to the patient.

5 Next, the present embodiment will be described below from the standpoint of flow path resistance. The flow path resistance is defined as the driving force required for sustaining a constant flow of 20  $\mu\text{l/sec}$  using water. As shown in Fig. 9, the measuring system for the flow path resistance  
10 has a container 91 containing water 90, which is the liquid used for the test, a pump 92 for transferring the suctioned water 90 under a pressure, a recorder 93 for recording the discharge pressure of the pump 92 (i.e., the driving force), and a needle mounting part 94 for detachably attaching the  
15 needle part, for which the sticking resistance is measured.

More specifically, the water 90 is pure water produced by a reverse osmosis membrane, and the pump 92 is a metering pump used generally for high-speed liquid chromatography. The needle mounting part 94 and the needle part are detachably connected by way of a screw.  
20

Specifically, as shown in Fig. 10, the needle part is connected to a known needle hub 97 with an internally threaded part 96 by way of adhesives or the like, and the internally threaded part 96 is screwed to an externally threaded part  
25 95 formed on the needle mounting part 94. The externally threaded part 95 includes a hollow tube part 95a, which is inserted into the proximal end of the needle part to introduce the water 90 into the needle part.

The recorder 93 records the discharge pressure of the  
30 pump 92 at a steady state when the flow quantity of the pump 92 is sustained at 20  $\mu\text{l/sec}$ .

The measurement of the flow path resistance was performed

for the same needle part 2 (example 1) according to the present embodiment used in the sticking resistance measurement, and was also performed with respect to two kinds of reference needles. One of the reference needles is a 31G needle that  
5 is the same as the needle used in the sticking resistance measurement as stated above, and the other is a 33G needle having a constant outer diameter of 0.203 mm for the entire length, which corresponds to the outer diameter of the distal end 21b of the puncturing part 21, and a constant inner diameter  
10 of 0.105 mm for the entire length.

Fig. 11 is a graph showing the results of the flow path measurement. As can be seen from the graph, the flow path resistance of the 31G needle was about 272 gf (2.67 N), the flow path resistance of the 33G needle was about 690 gf (6.76  
15 N), and the flow path resistance of the needle part 2 according to this embodiment was about 245 gf (2.40 N).

Thus, the flow path resistance of the needle part 2 is less than a half of the flow path resistance of the 33G (i.e., 350 gf (3.43 N)) despite the fact that the outer diameter  
20 of the distal end 21b of the needle part 2 is equivalent to that of the 33G needle.

More specifically, the 33G needle exhibits a flow path resistance of approximately 2.5 times the 31G needle, and the needle part 2 exhibits a flow path resistance of approximately 0.9 times the 31G needle. Thus, the needle part  
25 2 according to the present embodiment possesses better flow path resistance characteristics than the 31G and the 33G needles.

Fig. 12 is a table showing the results of the sticking  
30 and flow path resistance measurements for examples 2-12 having different dimensions. As is apparent from these results, one of the needle examples possesses a sticking resistance equal

to 7.1 gf, another of the needle examples possesses a sticking resistance of 7 gf, and all other needle examples possess a sticking resistance less than 7 gf. In addition, all of the needle examples possess a flow path resistance less than 350 5 gf. The needle examples thus all possess superior characteristics.

Next, the method of using the drug injection device 1 will be described. The drug solution 8 is sucked from a container such as a vial directly or via a rubber plug into 10 the internal space 41 of the main body 4 of the drug injection device 1. Then, the puncturing part 21 of the needle part 2 is used to percutaneously make a puncture in the body of the patient, which is the target of the drug solution injection. The distal end 21b of the puncturing part 21 is thinner than 15 the conventional needle. Therefore, it is possible to reduce irritation of the nerves and blood vessels related to the pain and/or damage to the nerves and blood vessels, thus resulting in less pain generation.

By pressing the plunger 5, the drug solution 8 in the 20 internal space 41 is injected through the passage 31 of the supporting part 3, the anchoring part 22 and the puncturing part 21 of the needle part 2 into various parts of the living body of the patient, e.g., intracutaneous and subcutaneous parts, muscles, mucous membranes, or various internal organs.

The anchoring part 22 provides a sufficient junction force against the supporting part 3 as its outer diameter is relatively large. Therefore, there is no possibility of the anchoring part 22 coming off from the supporting part 3. Moreover, the proximal end 21d of the puncturing part 21 30 provides sufficient strength as its outer diameter is relatively large. Therefore, the puncturing part 21 is prevented from breaking.

The inner diameters of the anchoring part 22 and the proximal end 21d of the puncturing part 21 are relatively large. Therefore, the flow path resistances of the anchoring part 22 and the puncturing part 21 are minimized. Consequently,  
5 the force required to press the plunger 5 and push out the drug solution 8 is smaller and the injection of the drug solution 8 is performed smoothly and is thus improved.

It should be understood that this invention is not limited to the particular embodiments shown and described above, but  
10 may be changed and modified without departing from the technical concept of this invention. For instance, the shape of the distal end 21b of the puncturing part 21 does not necessarily have to have a constant outer diameter over its entire length. For example, the distal end 21b can have a  
15 tapering shape as shown in Fig. 13. The profile lines of the cross-section along the axis of the distal end 21b can be straight or gradually curved.

As shown in Fig. 14, the outer diameter the puncturing part 21 can be gradually reduced from the proximal end 21d toward the slanted part 21a. The profile lines of the cross-section along the axis of the puncturing part 21 can be straight or gradually curved.

Compared to the construction in which the outer diameter is substantially constant for the entire length of the distal end 21b, the embodiments shown in Fig. 13 and Fig. 14 allow the outer diameter of the distal end 21b in the vicinity of the slanted part 21a to be smaller to thereby reduce the puncturing pain to the patient.

Moreover, because the internal diameter of the distal end 21b gradually reduces toward the slanted part 21a, the drug solution 8 is accelerated when it passes through the distal end 21b and thus flows out of the slanted part 21a

more powerfully.

Although embodiments described above and illustrated in the drawing figures depict the drug injection needle 10 as having only one puncturing part 21, it is possible to arrange 5 to have a plurality of puncturing parts 21 as well. With such an arrangement, it is possible to increase the injection volume of the drug solution 8, so that a more expedient effect of the drug can be anticipated as the drug solution 8 is distributed more efficiently into various parts of the living 10 body.

#### Industrial Applicability:

As described in the above, the outer diameter of the distal end of the puncturing part can be made smaller in 15 comparison with the known prior art practices. For that reason, irritation and damage caused by the puncturing part to blood veins and nerves, and related the pain, can be reduced. Thus, pain to the patient can be decreased. The proximal side outer diameter of the puncturing part is larger than the distal 20 side outer diameter, so that strength sufficient for making a puncture in the living body with the puncturing part can be secured or ensured. Therefore, it is possible to avoid situations in which it is not possible to make a puncture due to breakdown of the puncturing part, for example.

25 As the outer diameter of the anchoring part that extends through the supporting part has a larger diameter compared to the known design, the joint area between the anchoring part and the supporting part is increased to allow the anchoring part to be fixed on the supporting part more securely. Thus, 30 the liquid injection needle and the liquid injection device can be manufactured more easily despite the fact that the outer diameter of the distal end of the puncturing part is

relatively small.

Also, because the inner diameters of the proximal end of the puncturing part and the anchoring part are made larger, the flow path resistance during injection of the liquid into 5 the living body can be reduced. This reduces the force required for injecting the liquid and makes it possible to improve the injection of the fluid into the living body.

The principles, preferred embodiments and modes of operation of the present invention have been described in 10 the foregoing specification. However, the invention which is intended to be protected is not to be construed as limited to the particular embodiments disclosed. Further, the embodiments described herein are to be regarded as illustrative rather than restrictive. Variations and 15 changes may be made by others, and equivalents employed, without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the spirit and scope of the present invention as defined in the claims, be embraced 20 thereby.

## CLAIMS

1. A liquid injection needle comprising:  
a hollow needle part for injecting a liquid;  
5 a supporting part to which the needle part is fixed;  
said needle part comprising an anchoring part that  
extends through an inside of said supporting part and a  
puncturing part that extends from said supporting part for  
making a puncture in a living body; and  
10 said puncturing part having a distal side outer diameter  
equal to or greater than 0.1 mm and equal to or less than  
0.25 mm, and a proximal side outer diameter than said distal  
side outer diameter.
- 15 2. The liquid injection needle as claimed in Claim 1,  
wherein said proximal side outer diameter is equal to or greater  
than 0.3 mm and equal to or less than 2 mm.
- 20 3. The liquid injection needle as claimed in Claim 1,  
wherein said puncturing part has a total length equal to or  
greater than 1.5 mm and equal to or less than 15 mm.
- 25 4. The liquid injection needle as claimed in Claim 1,  
wherein said puncturing part consists of a distal end, a middle  
part and a proximal end, said distal end and said proximal  
end both having constant outer diameters over their entire  
lengths, and said middle part having an outer diameter that  
gradually reduces toward said distal end to smoothly connect  
said distal end and said proximal end.  
30
5. The liquid injection needle as claimed in Claim 1,  
wherein an outer diameter of said puncturing part gradually

decreases from said supporting part toward a tip of said puncturing part.

6. The liquid injection needle as claimed in Claim 1,  
5 wherein said puncturing part has a total length equal to or greater than 1.5 mm and equal to or less than 5 mm, and said distal side outer diameter is equal to or greater than 0.1 mm and equal to or less than 0.25 mm over a range that is 2/3 or more of said total length.

10

7. The liquid injection needle as claimed in Claim 1,  
wherein said puncturing part has a total length greater than 5 mm and equal to or less than 15 mm, and said distal side outer diameter is equal to or greater than 0.1 mm and equal  
15 to or less than 0.25 mm over a range that is 3/5 or more of said total length.

8. The liquid injection needle as claimed in Claim 1,  
wherein said liquid contains a drug that acts on a living  
20 body.

9. The liquid injection needle as claimed in Claim 1,  
wherein said liquid is self-administered.

25 10. The liquid injection needle as claimed in Claim 1,  
wherein the puncturing part possesses a sticking resistance equal to or less than 7 gram-force.

30 11. The liquid injection needle as claimed in Claim 1,  
wherein said needle part possesses a flow path resistance equal to or less than 350 gram-force under a sustained water flow rate of 20  $\mu$ l/sec.

12. A liquid injection needle comprising:  
a hollow needle part for injecting a liquid;  
a supporting part to which the needle part is fixed;  
5 said needle part comprising an anchoring part that extends through an inside of said supporting part and a puncturing part that extends from said supporting part for making a puncture in a living body,  
said puncturing part having a proximal side outer diameter greater than a distal side outer diameter; and  
10 said puncturing part having a sticking resistance equal to or less than 7 gram-force.

13. The liquid injection needle as claimed in Claim 12,  
15 wherein said liquid contains a drug that acts on a living body.

14. The liquid injection needle as claimed in Claim 12,  
wherein said liquid is self-administered.

20 15. The liquid injection needle as claimed in Claim 12,  
wherein the needle part possesses a flow path resistance equal to or less than 350 gram-force under a sustained water flow rate of 20  $\mu\text{l/sec}$ .

25 16. A liquid injection needle comprising:  
a hollow needle part for injecting a liquid;  
a supporting part to which the needle part is fixed;  
said needle part comprising an anchoring part extending  
30 through an inside of said supporting part and a puncturing part extending from said supporting part for making a puncture in a living body;

said puncturing part having a proximal side outer diameter greater than a distal side outer diameter; and

said needle part having flow path resistance equal to or less than 350 gram-force under a sustained water flow rate  
5 of 20  $\mu\text{l/sec}$ .

17. The liquid injection needle as claimed in Claim 16, wherein said liquid contains a drug that acts on a living body.

10

18. The liquid injection needle as claimed in Claim 16, wherein said liquid is self-administered.

15

19. A liquid injection device provided with said liquid injection needle as claimed in Claim 1, comprising a main body having an internal space adapted to contain said liquid, said supporting part being provided at one end of the main body, said needle part of said liquid injection needle being fixed on said supporting part to communicate with said internal  
20 space.

20. The liquid injection device as claimed in Claim 19, wherein said proximal side outer diameter is equal to or greater than 0.3 mm and equal to or less than 2 mm.

25

21. The liquid injection device as claimed in Claim 19, wherein said puncturing part has a total length equal to or greater than 1.5 mm and equal to or less than 15 mm.

30

22. The liquid injection device as claimed in Claim 19, wherein said puncturing part includes a distal end, a middle part and a proximal end, said distal end and said proximal

end both having constant outer diameters over their entire lengths respectively, and said middle part having an outer diameter that gradually reduces toward said distal end to smoothly connect said distal end and said proximal end.

5

23. The liquid injection device as claimed in Claim 19, wherein said puncturing part has an outer diameter that gradually decreases from said supporting part toward a tip of said puncturing part.

10

24. The liquid injection device as claimed in Claim 19, wherein said puncturing part has a total length equal to or greater than 1.5 mm and equal to or less than 5 mm, and said distal side outer diameter is equal to or greater than 0.1 mm and equal to or less than 0.25 mm over a range that is 2/3 or more of said total length.

25. The liquid injection device as claimed in Claim 19, wherein said puncturing part has a total length greater than 5 mm and equal to or less than 15 mm, and said distal side outer diameter is equal to or greater than 0.1 mm and equal to or less than 0.25 mm over a range that is 3/5 or more of said total length.

26. The liquid injection device as claimed in Claim 19, wherein said liquid contains a drug that acts on a living body.

27. The liquid injection device as claimed in Claim 19, wherein said liquid is self-administered.

28. The liquid injection device as claimed in Claim 19,

wherein said puncturing part possesses a sticking resistance equal to or less than 7 gram-force.

29. The liquid injection device as claimed in Claim 19,  
5 wherein said needle part possesses a flow path resistance equal to or less than 350 gram-force under a sustained water flow rate of 20  $\mu\text{l/sec}$ .

30. A liquid injection device provided with said liquid injection needle as claimed in Claim 12, comprising a main body having an internal space adapted to contain said liquid, said supporting part being provided at one end of the main body, said needle part of said liquid injection needle being fixed on said supporting part to communicate with said internal 15 space.

31. The liquid injection device as claimed in Claim 30, wherein said liquid contains a drug that acts on a living body.

20

32. The liquid injection device as claimed in Claim 30, wherein said liquid is self-administered.

33. The liquid injection device as claimed in Claim 30, 25 wherein said needle part possesses a flow path resistance equal to or less than 350 gram-force under a sustained water flow rate of 20  $\mu\text{l/sec}$ .

34. A liquid injection device provided with said liquid 30 injection needle as claimed in Claim 16, comprising a main body having an internal space adapted to contain said liquid, said supporting part being provided at one end of the main

body, said needle part of said liquid injection needle being fixed on said supporting part to communicate with said internal space.

5        35. The liquid injection device as claimed in Claim 34, wherein said liquid contains a drug that acts on a living body.

10      36. The liquid injection device as claimed in Claim 34, wherein said liquid is self-administered.

1/9

FIG. 1

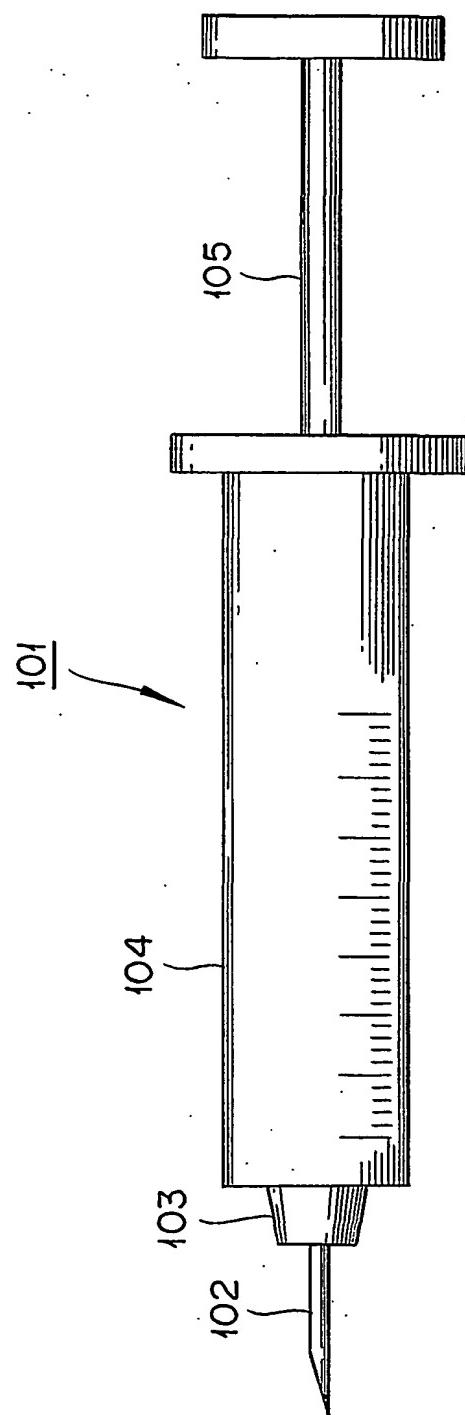


FIG. 2

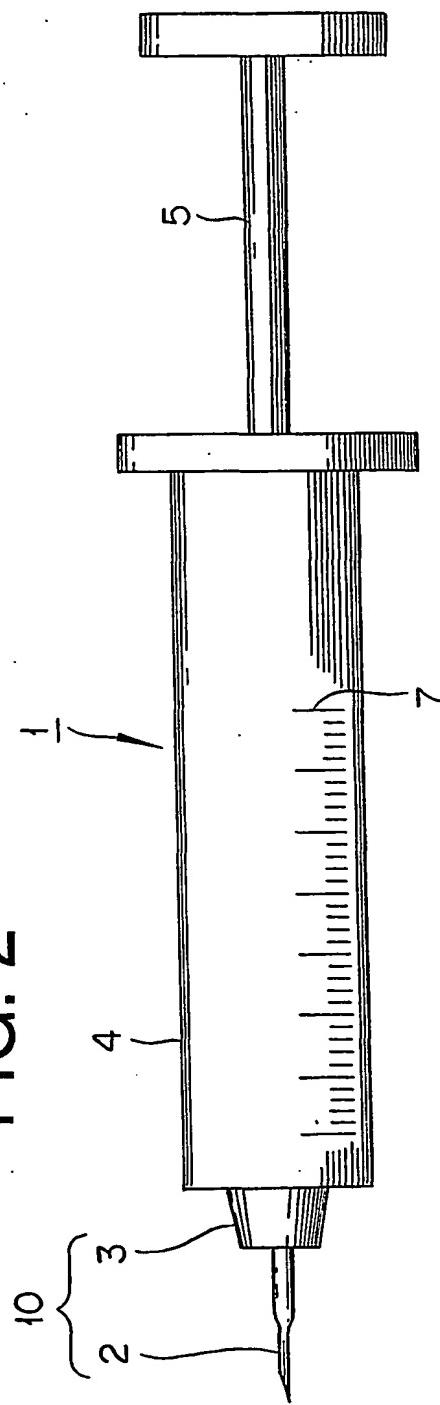
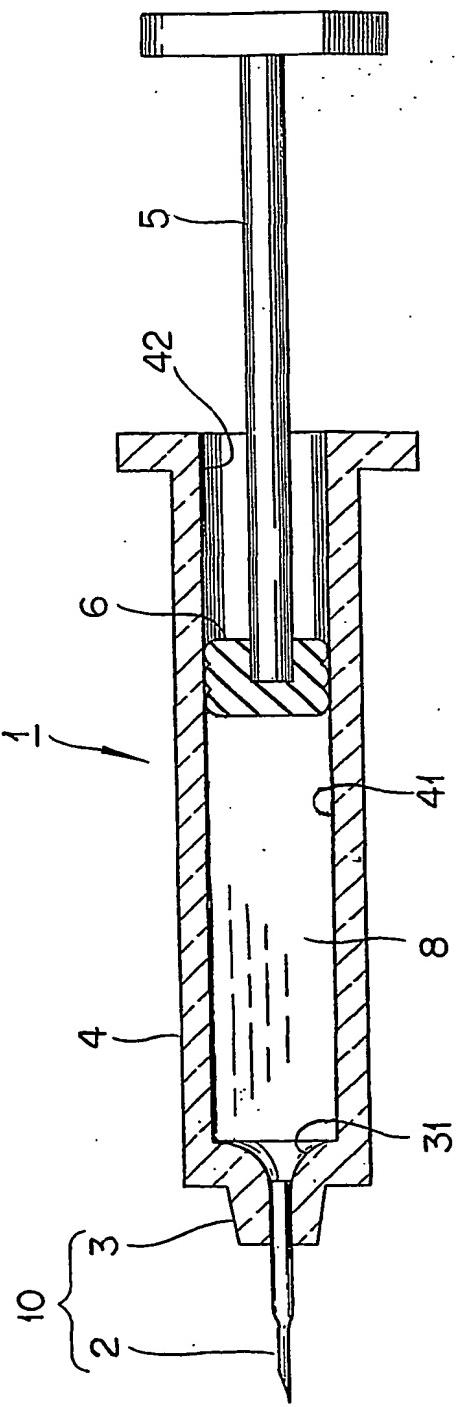
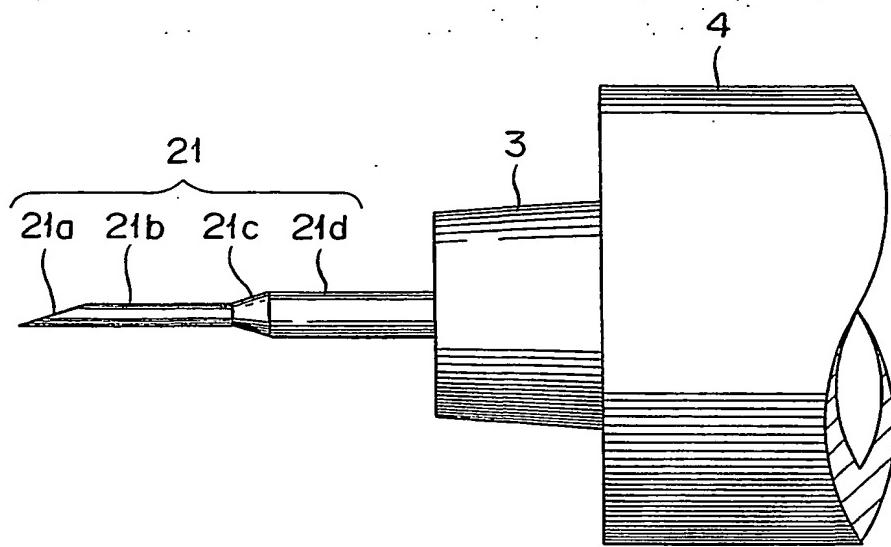
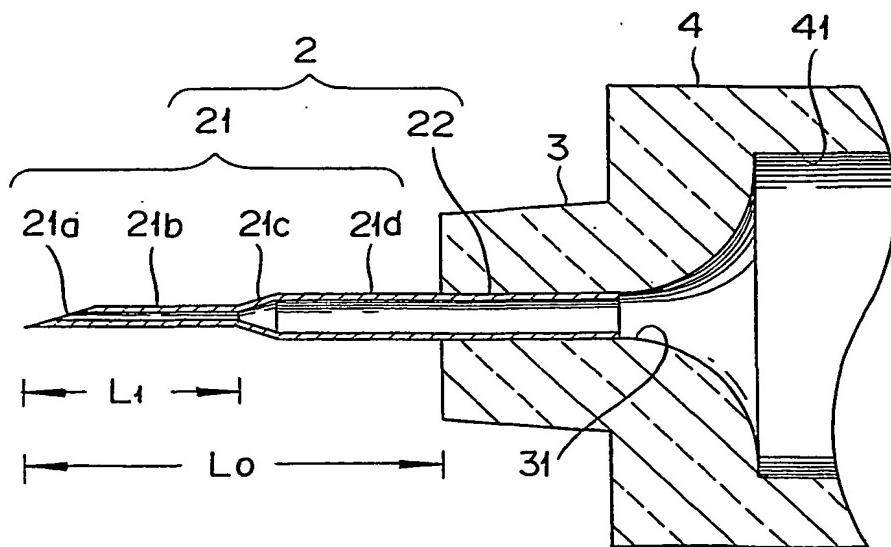


FIG. 3

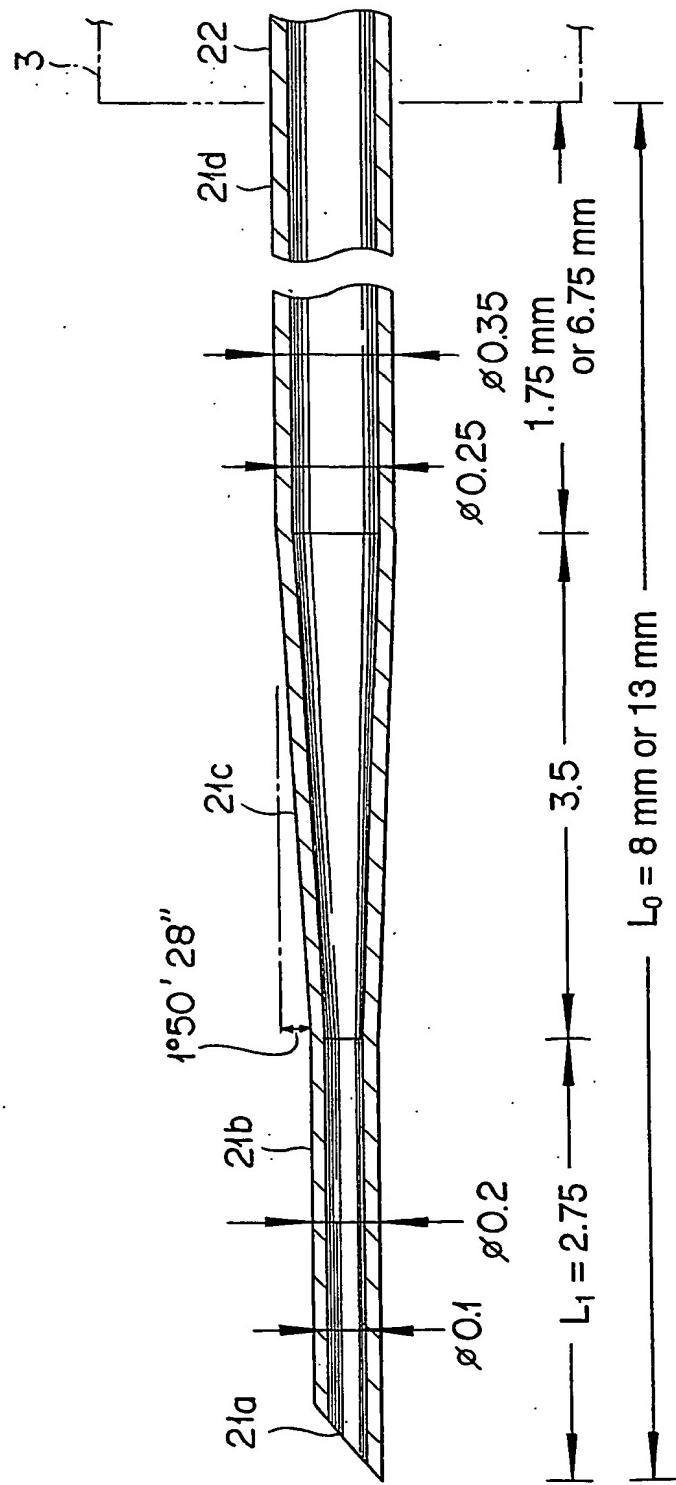


3/9

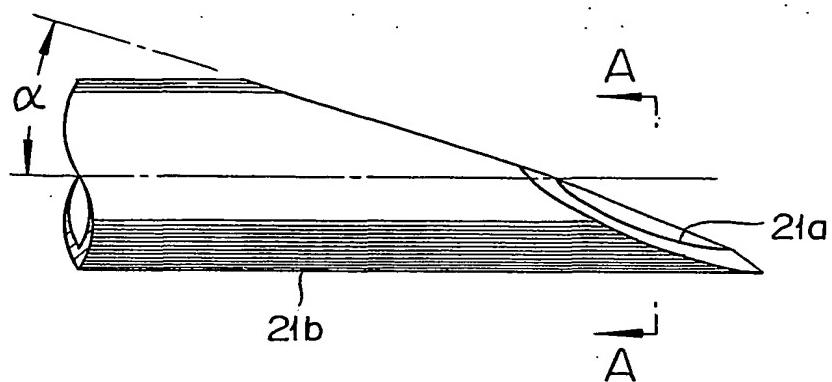
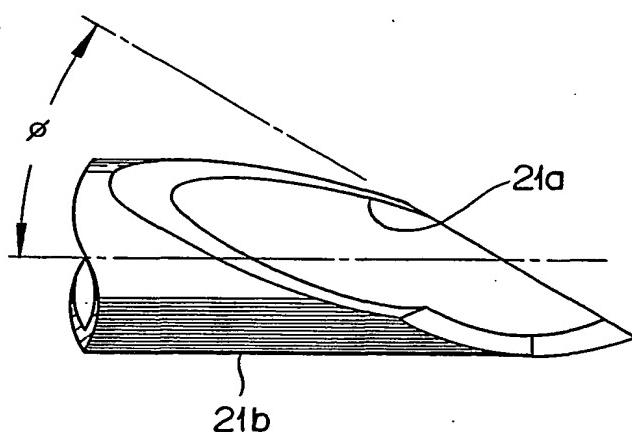
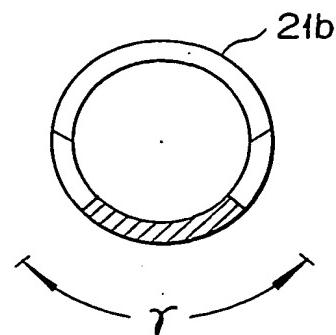
**FIG. 4****FIG. 5**

4/9

FIG. 6



5/9

**FIG. 7A****FIG. 7B****FIG. 7C**

6/9

FIG. 8

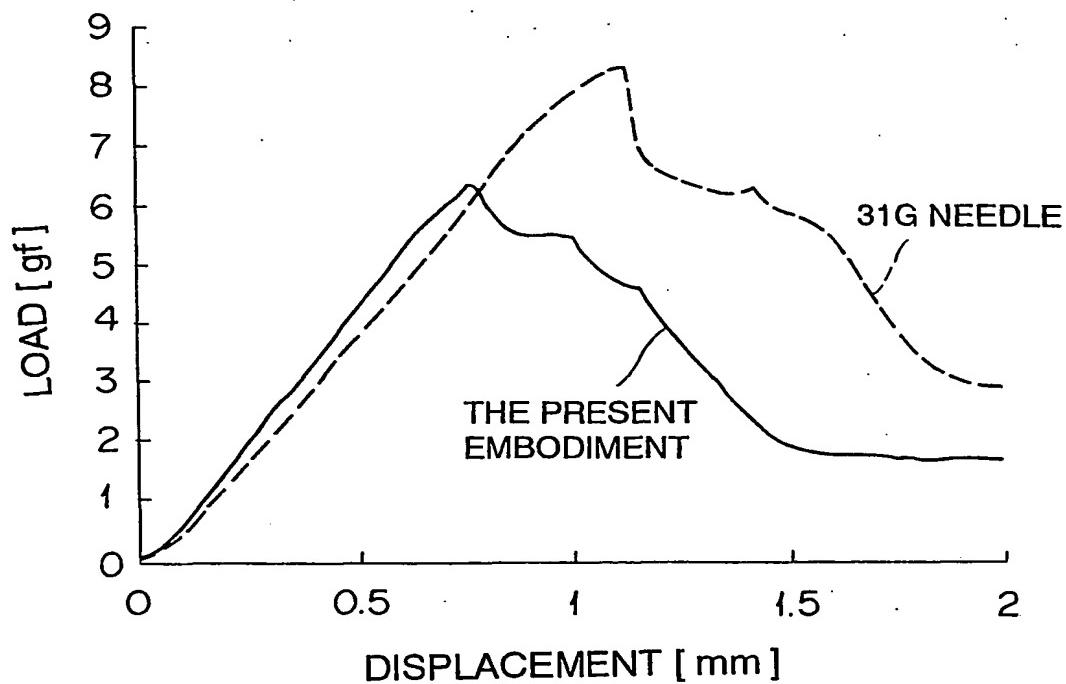
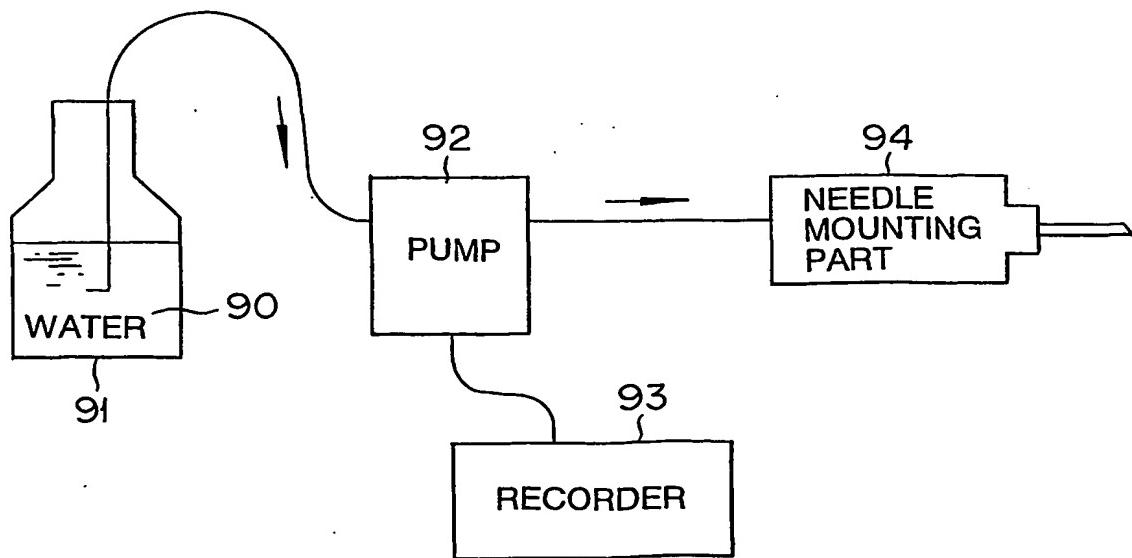


FIG. 9



7/9

FIG. 10

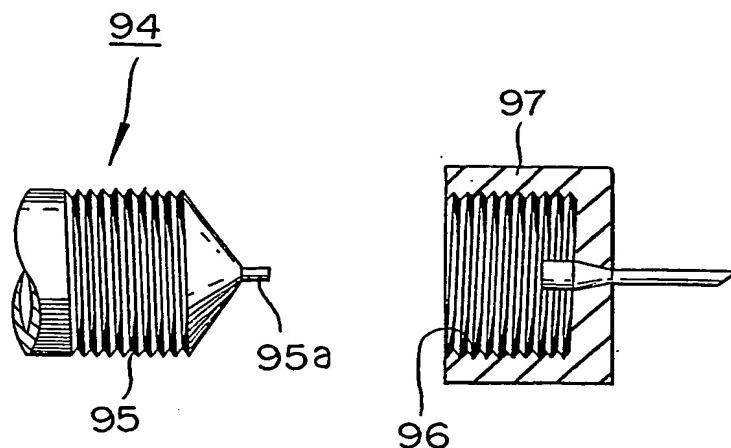


FIG. 11

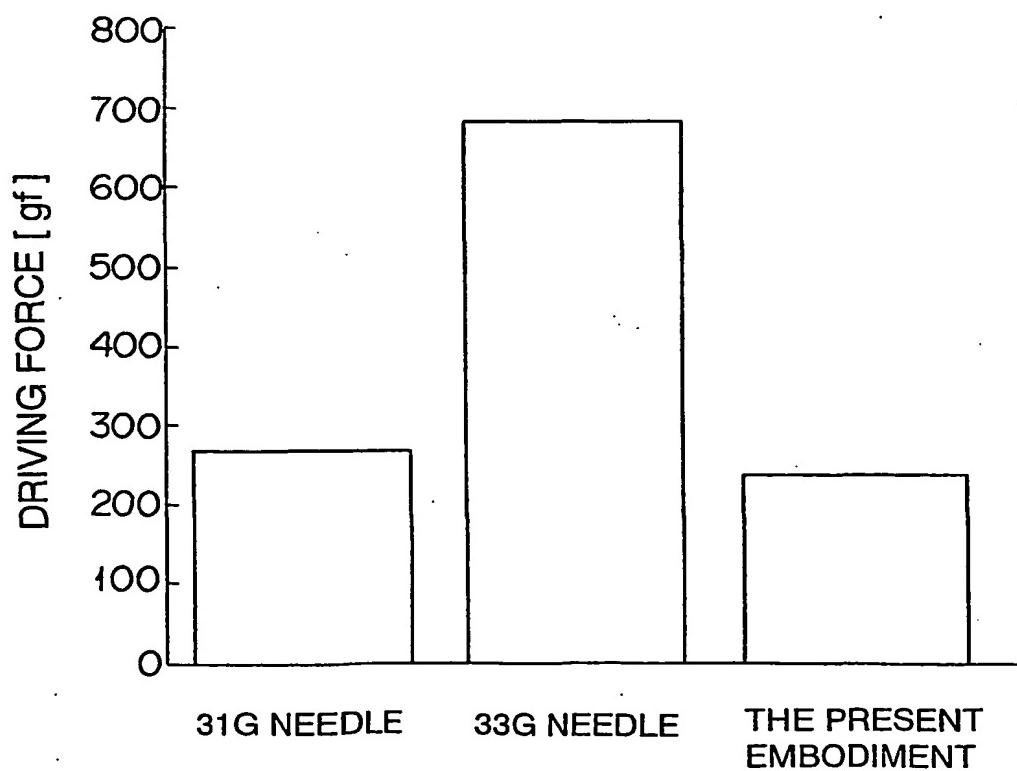
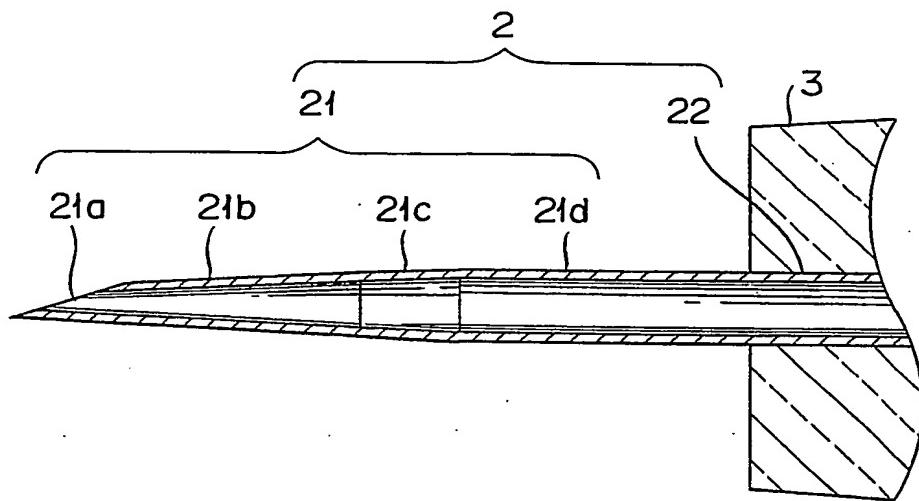
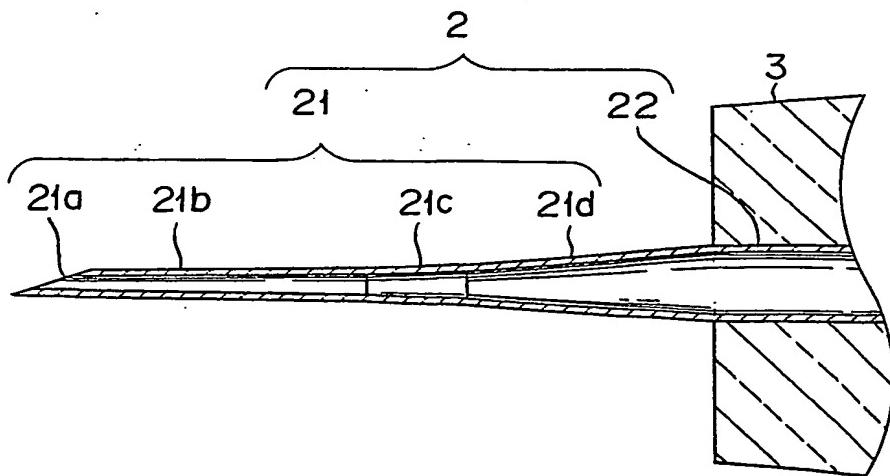


FIG. 12

8 / 9

	EXAMPLE										
	2	3	4	5	6	7	8	9	10	11	12
TOTAL LENGTH $L_0$ OF PUNCTURING PART 21 [mm]	13	13	13	13	13	13	13	13	13	13	13
LENGTH $L_1$ OF DISTAL END 21b [mm]	2.75	2.75	2.75	2.75	2.75	2	4	1	2.75	2	
OUTER DIAMETER OF PROXIMAL END 21d [mm]	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	
INNER DIAMETER OF PROXIMAL END 21d [mm]	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
OUTER DIAMETER OF DISTAL END 21b [mm]	0.18	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.22	0.22
INNER DIAMETER OF DISTAL END 21b [mm]	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.12	0.12
LENGTH OF MIDDLE PART 21c [mm]	3.5	3.5	3.5	3.5	3.5	3.5	5	4	3.5	3.5	5
FIRST GRINDING ANGLE $\alpha$ [°]	8.5	8.5	8.25	8.25	8.5	8.5	8.5	8.5	8.5	8.5	8.5
SECOND GRINDING ANGLE $\phi$ [°]	17	17	15	16.75	13	18	17	17	17	17	17
CROSS SECTIONAL ANGLE $\gamma$ [°]	130	130	120	120	140	129	130	130	130	130	103
STICKING RESISTANCE [gf]	5.4	5.4	6	6.2	6.4	6.4	5.5	5.5	5.5	7.1	7
FLOW PATH RESISTANCE [gf]	243	243	243	243	243	248	248	285	230	210	205

9/9

**FIG. 13****FIG. 14**

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/JP 02/00550A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	GB 542 619 A (MACGREGOR INSTR COMPANY) 20 January 1942 (1942-01-20) page 2, left-hand column, line 49 - line 61 page 3, left-hand column, line 20 - line 34 figures 1-3,7 ---	1,12,16, 19,30,34
A	US 5 951 528 A (PARKIN ADRIAN) 14 September 1999 (1999-09-14) column 3, line 16 - line 47 figures ---	1,12,16, 19,30,34



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

6 June 2002

Date of mailing of the international search report

21/06/2002

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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/JP 02/00550

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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